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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/473,165	12/28/1999	YOSHIHIKO HIGUCHI	20111-0035	9663

23594 7590 05/07/2003

JOHN S. PRATT  
KILPATRICK STOCKTON LLP  
1100 PEACHTREE  
SUITE 2800  
ATLANTA, GA 30309

EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/473,165

Applicant(s)

HIGUCHI ET AL

Examiner

LaToya L. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. In view of the appeal brief filed on September 11, 2002, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arai et al '347 in view of US Patent 5,071,746 to Wilk et al.

Arai et al '347 teach a multi-layer analysis element containing at least one hydrophilic polymer layer and a spreading layer on the hydrophilic layer. The hydrophilic layer contains colorimetric reagents and serves as the reagent layer (col. 3, lines 10-17). The multi-layer system also provides for a light-shielding (light-blocking) layer on the reagent layer. The light-shielding layer contains light shielding particles such as carbon black (col. 4, lines 39-62).

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Arai et al '347 further disclose that the light shielding layer is formed of fine particles (such as carbon black) dispersed in hydrophilic polymer binders such as polyvinyl alcohol (col. 3, lines 1-5 and col. 4, lines 39-47). At col. 5, lines 4-15, Arai et al '347 teach that the ratio of hydrophilic polymer binder to light-shielding particles is about 2.5-7.5 to 10. Arai et al '347 also disclose that single layers may be made to serve two or more functions (col. 3, lines 44-50).

Arai et al '347 differ from the instantly claimed invention in that the limitation of embedding the light-shielding particles in polymeric beads is not explicitly disclosed. Arai et al use dispersed in a polymer material.

Wilk et al teach dry measuring analytical test devices having a liquid absorbing first layer, a porous second layer and a reagent layer. The porous second layer includes a carrier and binding partner, which are embedded in the layer. The carrier may be a titanium dioxide material, known for its radiation blocking properties. Wilk et al teach advantages of using embedded particles in the layers in that sufficient adherence of the particles to the layer takes place, as well as the loading capabilities of the sample onto the layer are enhanced when the particles are embedded, resulting in a more rapid absorbency and a lesser volume of sample is required. See col. 5, lines 19-23 and lines 56-63.

It would have been obvious to one ordinary skill in the art to embed the radiation blocking particles into the light blocking layer in the Arai et al device to provide enhanced loading capabilities and decrease the amount of sample needed to carry out the test.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious to one of ordinary skill in the art, in view of the teachings of Arai et al and Wilk et al.

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***Response to Arguments***

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***


The declaration under 37 CFR 1.132 filed June 25, 2001 is sufficient to overcome the rejection of claim carbon black being used as the particular light shielding particle based upon Applicants' data submitted. The declaration provides evidence showing only carbon black and its unexpected results of being embedded in a polymer, versus being dispersed in a polymer. Applicant may choose to either incorporate carbon black into the independent claim or provide new showings that other light shielding particles, such as iron oxide, phthalocyanine blue and phthalocyanine green, provide unexpected results as well.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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May 5, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700